sequence that is identical or fully complementary to a sequence starting at nucleotide 1266 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein each segment of 30 contiguous nucleotides of said nucleotide sequence has at least 85% homology with a segment of 30 contiguous nucleotides of said reference sequence.

Please add new claims 41 and 42 as follows:

--41. The probe according to claim 5, wherein said probe has 7 to 100 nucleotides.--

--42. The primer according to claim 8, wherein said primer has 7 to 30 nucleotides.--

REMARKS

Claims 1, 2, 5, 7, 8, 10-27, 32, 34 and 36-42 are now pending. By the Office Action, claims 1 and 2 are allowed and claims 5, 7, 8, 10-27, 32, 34 and 36-40 are rejected. By this Amendment, claims 5, 8, 10, 17, 21 and 23 are amended, and claims 41 and 42 added. No new matter is added.

The attached Appendix includes marked-up copies of each rewritten claim (37 C.F.R. §1.121(c)(1)(ii)).

Applicants appreciate the courtesies shown to Applicants' representative by Examiner Navarro in the September 5 personal interview. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

I. §112 REJECTIONS

A. §112, First Paragraph, Enablement

Claims 5, 7, 8, 10-27, 32, 34 and 36-40 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicants respectfully traverse the rejection.

Specifically, the Office Action indicates that the claim language allows for an unspecified number of nucleotides upstream and/or downstream of the claimed probe/primer that can potentially impact the function of the probe/primer. The Office Action indicates that the disclosure is enabling for probes/primers that exclude additional nucleotides that could impact the function of the primers/probes. The Office Action suggests using the transitional phrase "consisting of" to exclude nucleotides that could impact the function of the primers/probes.

By this Amendment, claims 5, 8, 10, 17, 21 and 23 are amended to recite the transitional phrase "consisting essentially of." As stated by MPEP §2111.03, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). These claim amendments sufficiently address the Examiner's concern by excluding any additions that would materially affect the basic and novel characteristics of the probes/primers, as agreed in the September 5 personal interview.

B. §112, First Paragraph, Written Description

Claims 5, 7, 8, 10-27, 32, 34 and 36-40 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. Applicants respectfully traverse the rejection.

Specifically, the Office Action indicates that the written description supports probes/primers having homology to the disclosed sequence, but the claims read on fragments that may include nucleotide additions upstream or downstream of the homologous region of the fragment that could impact the function of the probe/primer. The Office Action indicates

that replacing the transitional phrase "comprising" with the transitional phrase "consisting of" avoids this problem. As discussed above in Section IA, the claims have been amended to recite the transitional phrase "consisting essentially of." The claims are now limited to the homologous fragment and additions that do not materially affect the basic and novel characteristics of the probe/primer, as agreed in the personal interview.

C. Conclusion

For at least the reasons discussed above, Applicants submit that claims 5, 7, 8, 10-27, 32, 34 and 36-41 satisfy the requirements of 35 U.S.C. §112, first paragraph. Reconsideration and withdrawal of the rejections are respectfully requested.

II. §102 REJECTIONS

Claims 5, 8, 10, 11, 17, 25, 26, 32, 34, 39 and 40 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,302,527 to Birkett et al. (hereinafter "Birkett"). Applicants respectfully traverse the rejection.

Independent claim 5 claims: "A probe for identifying Trypanosoma cruzi, consisting essentially of a sequence having at least 85% homology with a fragment of a nucleotide sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein said probe contains at least 5 and no more than 100 nucleotides."

Independent claim 8 claims: "A primer for amplifying a nucleotide sequence, consisting essentially of a sequence having at least 85% homology with a fragment of a nucleotide sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein said primer contains at least 5 and no more than 30 nucleotides."

Birkett discloses labeling an isolated DNA fragment using Klenow Polymerase with Random Priming by mixed hexomer oligonucleotides from the MultiPrime kit sold by

Amersham. The Office Action indicates that the MultiPrime Kit, and Random Priming kits in general, allegedly contain every possible nucleotide sequence of six consecutive nucleotides, and that the mixed hexomer oligonucleotides of Random Priming kits inherently anticipate the claimed probes/primers. Applicants respectfully disagree.

It is well known to those skilled in the art that 100% homology is not necessary for a primer to bind to a target sequence. Techniques that use Random Priming take advantage of this fact by using randomly generated hexomer primers. As the name indicates, the nucleotide sequences of the hexomers are random, and hexomers having a specific sequence are not intentionally generated. Random hexomer kits do not include every possible combination of six nucleotides, as every conceivable sequence is not necessary for successful priming.

In order for prior art to anticipate a claimed invention on the ground that a limitation is inherently disclosed in the reference, the inherency must be certain. The fact that a prior art reference may have the characteristics of the claimed product is not sufficient. Inherency must be a necessary result and not merely a possible result; the mere fact that a certain thing may result from a given set of circumstances is not enough. In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); Ex parte Keith and Turnquest, 154 USPQ 320, 321 (PTO Bd. Pat. Appl & Int. 1966).

For at least the reasons discussed above, neither claim 5 nor claim 8 is anticipated by Birkett, as agreed in the personal interview. Claims 10, 11, 17, 25, 26, 32, 34, 39 and 40 depend from either claim 5 or claim 8, and thus include all of the limitations of either claim 5 or claim 8. Thus, these dependent claims are not anticipated by Birkett for at least the same reasons as for claim 5 or claim 8, as agreed in the interview. Reconsideration and withdrawal of the rejection are respectfully requested.

III. CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance. Favorable consideration and prompt allowance of claims 5, 7, 8, 10-27, 32, 34 and 36-42 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number set forth below.

Respectfully submitted,

William P. Berridge
Registration No. 30,024

Philip A. Caramanica, Jr.
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WPB:PAC/jam

Attachment:
Appendix

Date: December 9, 2002

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION
Please grant any extension necessary for entry;
Charge any fee due to our Deposit Account No. 15-0461

APPENDIX

Changes to Claims:

Claims 41 and 42 are added.

The following is a marked-up version of the amended claims:

5. (~~Three~~ Four Times Amended) A probe for identifying Trypanosoma cruzi, ~~said probe~~ consisting essentially of a sequence having at least 85% homology with a fragment of a nucleotide sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein said probe contains at least 5 and no more than 100 nucleotides.

7. (Amended) The probe according to claim 5, wherein said probe ~~comprises~~ has 8 to 50 nucleotides.

8. (~~Three~~ Four Times Amended) A primer for amplifying a nucleotide sequence, ~~said primer~~ consisting essentially of a sequence having at least 85% homology with a fragment of a nucleotide sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein said primer contains at least 5 and no more than 30 nucleotides.

10. (~~Three~~ Four Times Amended) The primer according to claim 8, wherein said primer ~~comprises~~ consists essentially of a nucleotide sequence selected from the group consisting of SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10 and SEQ ID NO:12.

17. (~~Twice~~ Three Times Amended) The reagent according to claim 11, further comprising at least one primer ~~comprising~~ consisting essentially of a segment of at least five contiguous nucleotides of a nucleic acid ~~which comprises a nucleotide sequence~~ that is identical or fully complementary to a first sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO: 1 or the corresponding RNA sequence.

20. (~~Twice~~ Three Times Amended) The method according to claim 18, wherein before said DNA is exposed to said probe, said DNA is amplified in the presence of an enzymatic system with at least one primer, wherein said primer ~~comprises~~ consists essentially of a segment of at least five contiguous nucleotides of a nucleic acid sequence that is identical or fully complementary to a sequence identified in SEQ ID NO: 1 or the corresponding RNA sequence.

21. (~~Twice~~ Three Times Amended) A synthetic or isolated nucleic acid fragment that ~~comprises~~ consists essentially of a nucleotide sequence having at least 85% homology with a reference sequence that is identical or fully complementary to a sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein each segment of 30 contiguous nucleotides of said nucleotide sequence has at least 85% homology with a segment of 30 contiguous nucleotides of said reference sequence.

23. (~~Twice~~ Three Times Amended) A synthetic or isolated nucleic acid fragment that ~~comprises~~ consists essentially of a nucleotide sequence having at least 85% homology with a reference sequence that is identical or fully complementary to a sequence starting at nucleotide 1266 and ending at nucleotide 2207 of SEQ ID NO: 1 or the corresponding RNA sequence, wherein each segment of 30 contiguous nucleotides of said nucleotide sequence has at least 85% homology with a segment of 30 contiguous nucleotides of said reference sequence.